



Practitioner's Docket No. 2260/117

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent application

of _____

Inventor(s)

for _____

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Pflaum

Application No.: 10/614,534

Group No.: N/A

Filed: July 7, 2003

Examiner: N/A

For: **Process for the Preparation of Amorphous Atorvastatin**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

(Information Disclosure Statement--page 1 of 8)

CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10*

(When using Express Mail, the Express Mail label number is **mandatory**;

Express Mail certification is optional.)

I hereby certify that, on the date shown below, this correspondence is being:

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37 C.F.R. SECTION 1.8(a)

37 C.F.R. SECTION 1.10*

[x] with sufficient postage as first class mail.

☐ as "Express Mail Post Office to Addressee"

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☐ transmitted by facsimile to the Patent and Trademark Office.

Signature

Timothy M. Murphy, Esq.

Date: August 14, 2003

***WARNING:** Each paper or fee filed by "Express Mail" **must** have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e, requests for waiver of this requirement will **not** be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

NOTE: "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

NOTE: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

NOTE: The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

WARNING: "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

List of Sections Forming Part of This Information Disclosure Statement

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: disC.F.R.d unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☒ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
 - 7A. ☐ JEPO Search Report
 - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections _____, respectively, have been continued on ADDED PAGE(S).

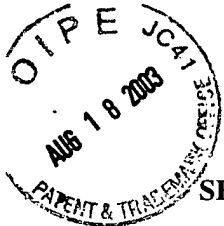
NOTE : "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

Section 1. Preliminary statements

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.

**SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)****IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Pflaum Attorney Docket: 2260/117
Serial No: 10/614,534 Art Group Unit: N/A
Date Filed: July 7, 2003 Examiner Name: N/A
Invention: **Process for the Preparation of Amorphous Atorvastatin**

**LIST OF PATENTS AND PUBLICATIONS FOR
APPLICANT'S INFORMATION DISCLOSURE STATEMENT**

| U.S. PATENT DOCUMENTS | | | | | | |
|--------------------------|------------------|-----------------|-----------------|------------------|-----------------------|----------------|
| Examiner Initials | Reference Number | Document Number | Issue Date | Inventor | Class/Subclass | |
| | AA | US 5,385,929 | 01/31/95 | Bjorge et al. | A61K 31/40 | |
| | AH | US 6,528,660 | 03/04/03 | Kumar et al. | 548/537 | |
| FOREIGN PATENT DOCUMENTS | | | | | | |
| Examiner Initials | Reference Number | Country Code | Document Number | Publication Date | Patentee or Applicant | Class/Subclass |
| | AB | WO | 00/71116 | 11/03/00 | Kumar et al. | A61K 31/40 |
| | AC | WO | 97/03958 | 07/08/96 | McKenzie | C07D 207/34 |
| | AD | WO | 97/03959 | 07/08/96 | Briggs et al. | C07D 207/34 |
| | AE | WO | 97/03960 | 07/16/96 | Lin et al. | C07D 207/34 |
| | | | | | | |

| OTHER DOCUMENTS | | | |
|-------------------|------------------|---------------|---|
| Examiner Initials | Reference Number | Author | Title of Article, Title of Journal, Volume Number, Page Numbers, Date |
| | AF | Baumann et al | The Convergent Synthesis of CI-981, an Optically Active, Highly Potent, Tissue Selective Inhibitor of HMG-CoA Reductase, 04/21/92 |
| | AG | | Database Chemabs 1998 |
| | | | |



Examiner Signature: _____

Date Considered: _____

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

Section 4. Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted

NOTE: *"A copy of any patent, publication or other information listed in an information disclosure statement is not required to be provided if it was previously cited by or submitted to the Office in a prior application, provided that the prior application is properly identified in the statement and relied upon for an earlier filing date under 35 U.S.C. 120." 37 C.F.R. section 1.98(d).*

WARNING: *"This exception to the requirement for copies of information does not apply to information which was cited in an international application under the Patent Cooperation Treaty." Notice of April 20, 1992 (1138 O.G. 37-41, 38).*

WARNING: *"Information which is cited or submitted to the Office in the parent application of a file wrapper continuing application under 37 C.F.R. section 1.62 will be part of the file before the examiner and need not be resubmitted in the continuing application. Likewise, the examiner will consider information cited or submitted to the Office in a parent application when examining a continuing application and thus this information need not be resubmitted unless applicant desires the information to be printed on the patent." Notice of April 20, 1992 (1138 O.G. 37-41, 37).*

WARNING: *While a copy of a non-English language item of information need not be submitted, if it was previously submitted to, or cited by, the Office in a prior application, provided it is properly identified in this statement and this application relies on that earlier filing date under 35 U.S.C. 120, nevertheless, the requirement in section 1.98(a)(3) for a concise explanation of non-English language information would not be satisfied by a statement that a reference was cited in the prosecution of a parent application. The concise explanation must explain the relevance, as presently understood by the person designated in section 1.56(c) most knowledgeable about the content of the information. Notice of January 9, 1992, 1135 O.G. 13-25, at 20.*

This application relies, under 35 U.S.C. section 120, on the earlier filing date of prior application SN.: 10/149,348, filed on June 5, 2003.

(complete the following, if applicable)

[] This application also relies, under 35 U.S.C. section 120, on the earlier filing date of prior application SN.: 0 / , filed on _____ (date).

The following references were submitted to, and/or cited by, the Office in the prior application(s) and, therefore, are not required to be provided in this application:

Section 6. Copies of Listed Information Items Accompanying This Statement

NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (1) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."

NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

(complete the following, if applicable)

☐ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

Section 10. Identification of Person(s) Making This Information Disclosure Statement

The person making this certification is

(check each applicable item)

(a) ☐ the inventor(s) who signs below

SIGNATURE OF INVENTOR

(type name of inventor who is signing)

(b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

SIGNATURE OF INVENTOR

(type name of inventor who is signing)


(c) ☒ the practitioner who signs below on the basis of the information:

(check each applicable item)

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.



SIGNATURE OF PRACTITIONER

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(type or print name of practitioner)

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